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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,222	02/05/2004	Jean Woloszko	CB-16	1215

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ARTHROCARE CORPORATION
680 VAQUEROS AVENUE
SUNNYVALE, CA 94085-3523

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,222

Applicant(s)

WOLOSZKO ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,11,12,16,18,19,24-26,28,35-39,48 and 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-10, 13-15, 17, 20-23, 27, 29-34, 40-47 and 49 is/are rejected.
- 7) ☒ Claim(s) 31,34 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Applicant's election of the species of Figure 13 in the reply filed on June 1, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that applicant has indicated that claims 1-11, 13-27 and 29-52 read on the elected embodiment. The examiner disagrees. It is the examiner's position that claims 1-3, 6-10, 13-15, 17, 20-23, 27, 29-34, 40-47 and 49 read on the elected embodiment. The remainder of the claims are drawn to various other embodiments. For example, the subject matter of claims 4, 5 and 50-52 are drawn to the embodiment of Figures 9A-9C; the subject matter of claim 16 is drawn to the embodiment of Figure 4, etc. Claims 4, 5, 11, 12, 16, 18, 19, 24-26, 28, 35-39, 48 and 50-52 are withdrawn from further consideration as being drawn to a non-elected species.

Claim Objections

Claims 31, 34 and 41 are objected to because of the following informalities: claims 31 and 41 should apparently read "is adapted to removably engage", and claim 34 should apparently have the "and" inserted between "portion" and "adapted" (line 5) to make the language clearer. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 23 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 makes no grammatical sense and appears to be missing a substantial portion of the claim language.

Claim 47 is unclear and appears to be impossible. This claim recites that energy is delivered to the tissue site prior to positioning the device at the surgical site. It is not clear how the device can deliver energy to the surgical site before it has been located there.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 8, 9, 10, 13-15, 20-23, 27, 30, 34, 40, 42-47 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Jahns et al (6,558,382).

As depicted in Figures 1 and 2, Jahns et al disclose a device comprising a shaft (12) with an electrode assembly disposed at the distal end of the shaft. The electrode assembly includes first and second electrodes (22,42) which may be connected to opposite poles of a power supply. Jahns et al disclose a thermochromic temperature

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sensor (36) which changes appearance as the temperature increases (see col. 7, lines 39-54). The thermochromic sensor is disposed in proximity to the electrodes on the electrode support (Figure 2). A cable (28) is connected to the shaft proximal end portion and connects the device to a power supply. The method of using the device to treat tissue is inherent to the disclosed structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 7, 8, 17, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahns et al (6,558,382) in view of the teaching of Truckai et al (2003/0216732).

The Jahns et al device has been addressed previously. Jahns et al disclose the use of a thermochromic material to indicate temperature in the vicinity of the electrode structure, but fails to disclose the specific use of leuco dye, or of the specific location of the material (i.e. surrounding the tip member).

Truckai et al also disclose providing a thermochromic material on an RF electrode device. In particular, Truckai et al disclose the various types of thermochromic materials as well as the temperature ranges (see para. 0143) and also discloses the use of the thermochromic material to surround an electrosurgical tip (Figure 28). To have provided the thermochromic material at any particular location

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around the tip or in any desired formation (i.e. in the shape of a band) to allow for visualization of the material is deemed an obvious design consideration.

To have provided the Jahns et al device with any well known thermochromic material reactive to any given temperature range would have been an obvious consideration for one of ordinary skill in the art, particularly since Truckai et al disclose the use of similar materials and temperature ranges as set forth in the instant application claims. To have further provided the thermochromic material in any configuration on an electrosurgical tip member to allow for ease of visualizing the material would have also been an obvious consideration in view of the teaching of Truckai et al.

Claims 1-3, 6-10, 13-15, 17, 20-23, 27, 29-34, 40-47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willink et al (6,254,600) in view of the teaching of Truckai et al (2003/0216732).

The Willink et al device is an electrosurgical probe essentially the same as that disclosed in the instant application. It includes an elongate shaft (108) and a bipolar arrangement of electrodes (104,112) just as in the instant application. Willink et al also disclose the particular connection means for connecting the device to an energy source (see, for example, Figure 3). Willink et al also disclose the use of a temperature sensing means for monitoring temperature, but fail to specifically disclose the use of a thermochromic material on the probe distal end to display temperature conditions.

Truckai et al, as previously addressed, disclose the use of thermochromic materials for providing a visual display of temperature conditions over a range of

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temperatures. Further, Truckai et al teach that it is known to coat the tip of an RF instrument with the thermochromic material in proximity to the electrode to provide visual indication of the temperature at the tissue site. The various configurations for providing the thermochromic material (i.e. as an annular band) to provide ease of visualization is deemed to be an obvious design consideration for one of ordinary skill in the art.

To have provided the Willink et al probe with a thermochromic material at the probe distal end to provide a visual display of the temperature in the vicinity of the electrodes would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Truckai et al.

Conclusion

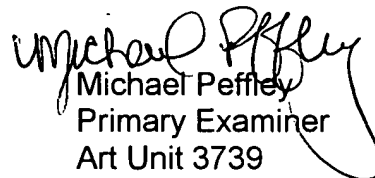
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schulze et al (5,599,350) and McClurken et al (2005/0033278) disclose alternative RF devices that utilize a thermochromic material to provide visual feedback of temperature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

Mp
August 8, 2005